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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

UNITED STATES OF AMERICA,

Plaintiff,

vs.

GRANDMA'S HERBS, INC.,
a corporation, and KEVIN PARR and
TRACEY PARR, individuals,

Defendant.

Case No. 4:21-cv-106-DN

**COMPLAINT FOR PERMANENT
INJUNCTION**

Judge David Nuffer

Plaintiff, United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Grandma's Herbs, Inc., a corporation, and Kevin Parr and Tracey Parr, individuals (collectively, "Defendants"), from violating:

A. 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, of new drugs, as defined in 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i); and

B. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, of articles of drug, as defined in 21 U.S.C. § 321(g), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Grandma's Herbs, Inc. ("Grandma's Herbs" or "the company") is a Utah corporation with its principal place of business at 221 W. 200 S, Saint George, Utah 84770 ("Defendants' establishment"), within the jurisdiction of this Court.

5. Defendant Kevin Parr is the president and co-owner of Grandma's Herbs. Defendant Kevin Parr has the authority to hire and fire employees, and oversees all operations at the company, including purchasing, quality control, sanitation, product formulation, and product labeling. Defendant Kevin Parr is also responsible for the company's website, grandmasherbs.com, on which Defendants' products are sold online.

6. Defendant Tracey Parr is the vice-president and co-owner of Grandma's Herbs. Defendant Tracey Parr's responsibilities include reviewing and approving incoming finished product from Defendants' contract manufacturer, and executing customer orders.

7. Defendants Kevin Parr and Tracey Parr perform their duties at Defendants' establishment, within the jurisdiction of this Court.

DEFENDANTS' OPERATIONS

8. Defendants label, hold, sell, and distribute articles of drugs from Defendants' establishment.

9. Defendants operate a website, grandmasherbs.com, which is used to promote and sell their products. Consumers can purchase Defendants' products directly from this website. Defendants distribute a leaflet along with their products.

DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS

10. It is a violation of the Act to introduce or deliver for introduction, or cause to be introduced or delivered for introduction, into interstate commerce a "new drug" that is neither approved by the United States Food and Drug Administration ("FDA") nor exempt from approval. 21 U.S.C. § 331(d). Specifically, a "new drug" may not be introduced or delivered for introduction, or caused to be introduced or delivered for introduction, into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j).

Some of Defendants' Products Are Drugs

11. A product is a drug if, among other things, it is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease[.]” 21 U.S.C. § 321(g)(1)(B). The intended use of a product may be determined from any relevant source, including product labeling and the circumstances surrounding the distribution of the article.

12. The Act defines “label” as, among other things, “a display of written, printed, or graphic matter upon the immediate container of any article,” 21 U.S.C. § 321(k); and “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(m).

13. Defendants’ products are intended for use to diagnose, cure, mitigate, treat, and/or prevent numerous diseases, including, but not limited to, respiratory tract infections, ulcers, heart disease, autoimmune disorders, and epilepsy. Defendants have stated such intended uses on their product labeling, including their website, grandmasherbs.com, and leaflets that Defendants distribute with their products. The intended uses described on Defendants’ labeling include, but are not limited to, the following (listed by ingredient/product; claim(s); and source):

A. Allergy Defense: “diminishes some of the mucous production and soothes and relaxes the inflamed soft tissues that are affected by a typical allergic reaction” and “is a preventative product and should be taken before and during seasons symptoms normally occur” (product leaflet);

B. Bright Eyes: “has [] been used for pink eye” (product leaflet);

C. Astragalus root [an ingredient in Defendants’ Allergy Defense]: “help[s] prevent heart disease, and immunodeficiency virus” and is “known to have antimicrobial,

antiviral and anti-inflammatory capabilities” (<https://www.grandmasherbs.com/packages/allergy-package/> (accessed on 2/3/2021));

D. Devil’s claw [an ingredient in Defendants’ Arth-FX]: “has also been used as an analgesic [and] [a]nalgesics effectively aids [sic] in dealing with discomforts related to pain” (product leaflet);

E. Echinacea [an ingredient in Defendants’ Allergy Defense and Immune Enhancer]: “natural remedies for urinary tract infections, upper respiratory tract infections, colds and slow-healing wounds” (<https://www.grandmasherbs.com/packages/allergy-package/> (accessed on 2/3/2021); and <https://www.grandmasherbs.com/herbal-products/immune-enhancer> (accessed on 2/4/2021));

F. Eyebright [an ingredient in Defendants’ Allergy Defense]: “is taken by mouth to treat swollen (inflamed) nasal passages, allergies, hay fever, common cold, bronchial conditions, and inflamed sinuses (sinusitis) [and] is also used for coughs, ‘pink eye’ (conjunctivitis), earaches, epilepsy, headaches, hoarseness, inflammation, jaundice, runny nose, skin ailments, and sore throat” (<https://www.grandmasherbs.com/packages/allergy-package/> (accessed on 2/3/2021));

G. Goldenseal root [an ingredient in Defendants’ Bright Eyes]: “for a variety of conditions ranging from respiratory issues to stomach ailments like ulcers” and “for colds and other respiratory tract infections, allergic rhinitis (hay fever), ulcers” (<https://www.grandmasherbs.com/herbal-products/bright-eyes> (accessed on 2/3/2021));

H. Hydrangea [an ingredient in Defendants’ Kidney Cleansing & Strengthening]: “[i]t is suggested that hydrangin is the constituent that makes hygrandeas

effective against kidney stones” (<https://www.grandmasherbs.com/herbal-products/kidney/> (accessed on 2/4/2021));

I. Myrrh [an ingredient in Defendants’ Nature’s Biotic]: “traditional or historical uses range from indigestion and ulcers to colds, coughs and lung congestion [and it] was even used for such things as leprosy” (<https://www.grandmasherbs.com/herbal-products/natures-biotic> (accessed on 2/9/2021)); and

J. Reishi Mushroom [an ingredient in Defendants’ Allergy Defense]: “studies indicate that reishi mushrooms are capable of offering protection against numerous diseases or illnesses, including; inflammation, fatigue (including chronic fatigue syndrome), frequent infections (urinary tract, bronchitis, respiratory infections, etc.), liver disease, digestive problems, stomach ulcers and leaky gut syndrome, skin disorders, autoimmune disorders, viruses, and many others” (<https://www.grandmasherbs.com/packages/allergy-package/> (accessed on 2/3/2021)).

14. The intended uses set forth in the labeling for the products identified in Paragraph 13, as well as for many other of Defendants’ products, render those products drugs within the meaning of the Act.

Defendants’ Drugs Are Unapproved New Drugs

15. Under the Act, a drug is a “new drug” if its “composition . . . is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof[.]” 21 U.S.C. § 321(p)(1).

16. Defendants' drugs are "new drugs" as defined in 21 U.S.C. § 321(p)(1) because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

17. None of Defendants' drugs is the subject of an FDA-approved NDA or ANDA, or an effective IND.

18. Because Defendants' drugs are unapproved new drugs, Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of unapproved new drugs.

DEFENDANTS DISTRIBUTE MISBRANDED DRUGS

19. Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1), because their labeling fails to bear "adequate directions for use" and the drugs do not fall within a regulatory exemption from that requirement. *See, e.g.*, 21 C.F.R. § 201.115.

20. Defendants' drugs are prescription drugs for which adequate directions for lay use cannot be written, by definition. A prescription drug is "[a] drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A).

21. Because Defendants' prescription drugs are unapproved new drugs, as described above, they cannot qualify for an exemption from the requirement for adequate directions for use. 21 C.F.R. §§ 201.100(c)(2), 201.115. Thus, these drugs are misbranded under 21 U.S.C. § 352(f)(1).

22. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of misbranded drugs.

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

23. Defendants primarily sell their drugs through their website, grandmasherbs.com, and an Amazon account. Defendants ship approximately 70% of their finished products from Utah to out-of-state individuals and wholesalers, including to Colorado and Texas. Such shipment constitutes the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of 21 U.S.C. § 331(d), and of misbranded drugs in violation of 21 U.S.C. § 331(a).

DEFENDANTS' HISTORY OF VIOLATIVE CONDUCT

24. Defendants are aware that their practices violate the Act. FDA has repeatedly warned Defendants about their violative conduct and that continued violations could lead to enforcement action, including an injunction.

25. FDA sent a Warning Letter to Defendants on September 15, 2017 (“Warning Letter”), after conducting a review of the company’s website, grandmasherbs.com. The Warning Letter informed Defendants that certain of their drugs were unapproved new drugs and/or misbranded drugs. The Warning Letter further cautioned that failure to promptly correct the violations, and prevent future ones, could lead to enforcement action, including an injunction. Defendants did not respond to the Warning Letter.

26. FDA inspected Defendants’ establishment between September 18 and 24, 2018 (“2018 Inspection”). During that inspection, the FDA investigator identified and discussed with

Defendant Kevin Parr the continued presence of disease claims on the company's website, grandmasherbs.com and in other labeling (e.g., leaflets that Defendants distribute with their products), many of which were the same or similar to those cited in the Warning Letter. During that inspection, Defendant Kevin Parr indicated that Defendants would correct these claims. Defendant Kevin Parr subsequently submitted a written response to FDA; however, this response did not address the disease claims.

27. Due to the continued presence of disease claims in Defendants' product labeling and Defendants' repeated failure to correct such claims, FDA requested a regulatory meeting with Defendant Kevin Parr at FDA's Denver District Office to discuss any corrective actions Defendants may have taken to come into compliance with the Act and its implementing regulations. During the regulatory meeting held on March 5, 2019 ("2019 Regulatory Meeting"), FDA personnel explained to Defendant Kevin Parr that the labeling for Defendants' products continued to contain disease claims, suggested he hire a consultant, and reiterated that future noncompliance could lead to enforcement action, including an injunction.

28. FDA most recently inspected Defendants' establishment between January 6 and 10, 2020. During the inspection, the FDA investigator again identified and discussed with Defendant Kevin Parr the continued presence of disease claims on the company's website and in other labeling (e.g., leaflets that Defendants distribute with their products), many of which were the same or similar to those cited in the Warning Letter and discussed during the 2018 Inspection and 2019 Regulatory Meeting. FDA reiterated that Defendants' continued noncompliance could lead to enforcement action, including an injunction. Defendant Kevin Parr again stated that Defendants would correct these claims; however, to date, Defendants have failed to do so. On

February 3–9, 2021, FDA reviewed the company’s website, and confirmed the continued presence of disease claims there.

29. Thus, despite repeated notifications, Defendants remain unable or unwilling to comply with the Act. Unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any unapproved new drug; and

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any drug that is misbranded under 21 U.S.C. § 352(f)(1);

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from introducing or delivering for introduction, or causing the introduction or delivery for introduction into interstate commerce, of any drug unless and until an approved new drug application,

abbreviated new drug application, or investigational new drug application is filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drug;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any drug, or to holding drugs for sale after shipment of one or more of their components in interstate commerce, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Dated: October 18, 2021

Respectfully submitted,

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